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NOTICE OF ALLOWANCE AND FEE(S) DUE

2202

7590

09/04/2009

BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/04/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,902	08/17/2006	Takaji Wakita	1254-0321PUS1	2324

TITLE OF INVENTION: NUCLEIC ACID CONSTRUCT CONTAINING FULLLENGTH GENOME OF HUMAN HEPATITIS C VIRUS, RECOMBINANT FULLLENGTH VIRUS GENOME-REPLICATING CELLS HAVING THE NUCLEIC ACID CONSTRUCT TRANSFERRED

THEREINTO AND METHOD OF PRODUCING HEPATITIS C VIRUS PARTICLE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	12/04/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

(571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 2292 7590 09/04/2009 Certificate of Mailing or Transmission BIRCH STEWART KOLASCH & BIRCH I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. PO BOX 747 FALLS CHURCH, VA 22040-0747 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/589,902 08/17/2006 Takaji Wakita 1254-0321PUS1 2324 TITLE OF INVENTION: NUCLEIC ACID CONSTRUCT CONTAINING FULLLENGTH GENOME OF HUMAN HEPATITIS C VIRUS, RECOMBINANT FULLLENGTH VIRUS GENOME-REPLICATING CELLS HAVING THE NUCLEIC ACID CONSTRUCT TRANSFERRED THEREINTO AND METHOD OF PRODUCING HEPATITIS C VIRUS PARTICLE APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$0 \$1810 12/04/2009 **EXAMINER** ART UNIT CLASS-SUBCLASS LUCAS, ZACHARIAH 1648 424-228100 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo ■ Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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BIRCH STEWART KOLASCH & BIRCH			LUCAS, ZACHARIAH	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747		1648		
		DATE MAILED: 09/04/2009		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 306 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 306 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)
Examiner-Initiated Interview Summary	10/589,902	WAKITA ET AL.
Examiner initiated interview Canimary	Examiner	Art Unit
	Zachariah Lucas	1648
All Participants:	Status of Application:	_
(1) Zachariah Lucas.	(3)	
(2) <u>Susan W. Gorman</u> .	(4)	
Date of Interview: <u>19 August 2009</u>	Time:	
Type of Interview: ☐ Telephonic ☐ Video Conference ☐ Personal (Copy given to: ☐ Applicant ☐ Applic Exhibit Shown or Demonstrated: ☐ Yes ☐ No If Yes, provide a brief description: .	cant's representative)	
Part I.		
Rejection(s) discussed: NA		
Claims discussed: 11, 18		
Prior art documents discussed: NA		
Part II.		
SUBSTANCE OF INTERVIEW DESCRIBING THE GENE See Continuation Sheet	ERAL NATURE OF WHAT WAS	DISCUSSED:
Part III.		
 It is not necessary for applicant to provide a separate directly resulted in the allowance of the application. The of the interview in the Notice of Allowability. It is not necessary for applicant to provide a separate did not result in resolution of all issues. A brief summa 	ne examiner will provide a written record of the substance of the	en summary of the substance interview, since the interview
/Zachariah Lucas/ Primary Examiner, Art Unit 1648	(Applicant/Applicant's Representat	ive Signature – if appropriate)

Continuation of Substance of Interview including description of the general nature of what was discussed: The Examiner indicated that the claims were in allowable condition, except that claim 11 should be amended to read on "an isolated" cell, and claim 18 should include an active step other than "using the particle as an antigen." With respect to claim 18, the Examiner suggested that the claim be amended to read on - - A method for producing a hepatitis C immunogenic composition comprising mixing the particles according to claim 13 with a pharmaceutically acceptable excipient.- - Support for this amendment may be found on page 23 of the application as filed. The Applicant agreed to the amendments.